

# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

## I. GENERAL INFORMATION

Device Generic Name: Antibody to Hepatitis C Virus (Anti-HCV) Rapid Assay

Device Trade Name: OraQuick® HCV Rapid Antibody Test  
OraQuick® HCV Rapid Antibody Test Kit Control

Applicant's Name and Address: OraSure Technologies, Inc.  
220 East First Street  
Bethlehem, PA 18015

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P080027

Date of FDA Notice of Approval: June 25, 2010

Expedited: Not Applicable

## II. INDICATIONS FOR USE

The OraQuick® HCV Rapid Antibody Test is a single-use immunoassay for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in venipuncture whole blood specimens (EDTA, sodium heparin, lithium heparin, and sodium citrate) from individuals 15 years or older. The OraQuick® HCV Rapid Antibody Test results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HCV (state of infection or associated disease not determined) in persons with signs or symptoms of hepatitis and in persons at risk for hepatitis C infection.

## III. CONTRAINDICATIONS

None

#### IV. WARNINGS AND PRECAUTIONS

- Sale of the OraQuick HCV Rapid Antibody Test is restricted to health care professionals:
  - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and
  - where there is assurance that operators will receive and use the instructional materials.
- This assay has not been FDA approved for use in patient populations without signs, symptoms, or not at risk for hepatitis C infection.
- Not for use in screening whole blood, plasma, or tissue donors. Performance characteristics have not been established for testing a pediatric population less than 15 years of age or for pregnant women.

##### For in vitro Diagnostic Use

- The package insert must be read completely before using the product.
- Follow the instructions carefully when performing the OraQuick® HCV Rapid Antibody Test, failure to do so may cause an inaccurate test result.
- Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.<sup>1</sup>
- This kit has been approved for use with venipuncture whole blood specimens only. Use of this test kit with specimen types other than those specifically approved for this device may cause inaccurate test results.
- This test is not intended to be used to monitor individuals who are undergoing treatment.
- This test should be performed at temperatures in the range of 15°-37°C (59°-99°F). If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature (15°-37°C, 59°-99°F) before performing testing.
- Do not use if the test kit is exposed to temperatures outside of the recommended storage temperature (2°-30°C, 36°-86°F), or is tested outside of the operating temperature (15°-37°C, 59°-99°F).

##### Safety Precautions

- Handle specimens and materials in contact with specimens as if capable of transmitting infectious agents.
- Wear disposable gloves while handling and testing blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
- For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens

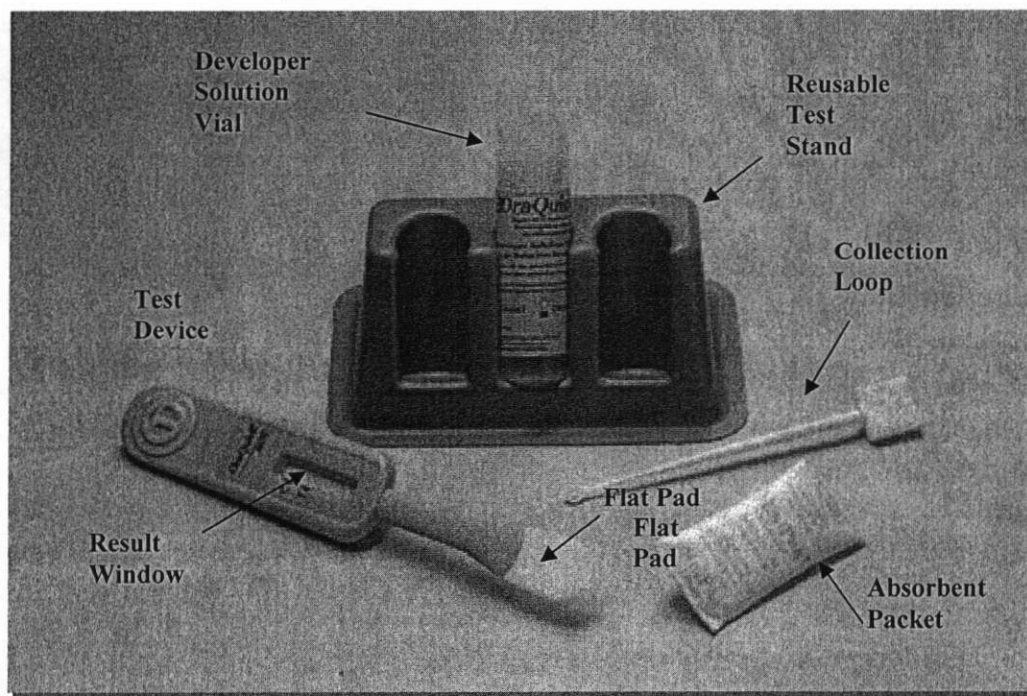
in Health-Care Settings”<sup>4</sup> and “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis”.<sup>2</sup>

#### Device Handling Precautions

- Use all Specimen Collection Loops, Test Devices, and Developer Solution Vials only once and dispose of properly (see Safety Precautions). Do not reuse any of these test components.
- Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
- Inspect the Divided Pouch. If the Divided Pouch has been damaged, discard the Divided Pouch and its contents and select a new Divided Pouch for testing.
- Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.
- Avoid microbial contamination and exercise care in handling the kit components.
- To ensure accurate results, the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing the specimen into the Developer Solution.
- Adequate lighting is required to read a test result.

#### V. DEVICE DESCRIPTION

The OraQuick<sup>®</sup> HCV Rapid Antibody Test kit is comprised of a divided pouch containing a test device with an absorbent packet and a labeled developer solution vial. Also included in the kits are reusable test stands, specimen collection loops, and a package insert.



The OraQuick® HCV Rapid Antibody Test utilizes an indirect lateral flow immunoassay method to detect antibodies to both structural and non-structural HCV proteins. The device utilizes synthetic peptides and recombinant antigens from the core, NS3, and NS4 regions of the HCV genome, that are immobilized as a single test line on the assay strip. Antibodies reacting with these peptides and antigens are visualized by colloidal gold labeled with protein A generating a visible line in the test zone for a reactive sample.

The OraQuick® HCV Rapid Antibody Test Kit Controls are available separately for use only with the OraQuick® HCV Rapid Antibody Test. The Kit Controls are human plasma-based reagents and are specifically formulated and manufactured to ensure proper performance of the test. The HCV Positive Control will produce a reactive reddish-purple line at the Test Zone (T Zone). The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the T Zone). Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

#### **VI. ALTERNATIVE PRACTICES AND PROCEDURES**

There are several other alternatives for the detection of antibodies to HCV. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

Determination of the presence of anti-HCV in patients may be achieved by using a variety of commercially available FDA approved serological tests. Anti-HCV test results are used in combination with a physician's assessment and other laboratory test results, in order to establish a diagnosis of infection with HCV.

#### **VII. MARKETING HISTORY**

The product has been commercialized in the countries comprising the European Union. This product has not been withdrawn from any market for any reason. The (device) has not been marketed in the United States.

#### **VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH**

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

A false positive result using an anti-HCV test would not be considered a patient or public health concern since a reactive result would be followed-up with supplemental tests, e.g., polymerase chain reaction (PCR) for detection of HCV RNA and / or strip immunoblot assay (SIA) to confirm infection and/or determine disease state. Treatment of the patient with chronic HCV infection is initiated only after extensive clinical, laboratory and behavioral assessment in order to assess eligibility and ability to comply with therapy.

A false negative anti-HCV result in a diagnostic setting may cause an HCV infected patient to remain undetected. This could be a safety concern for both the patient and the public, since such individuals may be capable of transmitting HCV infection. However, in patients where the suspicion of HCV infection is high, HCV RNA testing is often used to identify viremic individuals.

For the specific adverse events that occurred in the clinical studies, please see Section X below.

## **IX. SUMMARY OF PRECLINICAL STUDIES**

The performance characteristics of the OraQuick® HCV Rapid Antibody Test were evaluated in the non-clinical studies performed at OraSure Technologies, Inc.

### **A. Laboratory Studies**

#### **Biocompatibility**

The OraQuick® HCV device housing biocompatibility testing was completed by NAMSA (North American Science Associates) located at 6750 Wales Road, Northwood, Ohio. All testing was compliant with FDA Good Laboratory Practice (GLP) Requirements 21 CFR part 58. All testing used the OraQuick® HCV device housings (Top PN 3001-1745 and Base PN 3001-1746). Results from all studies demonstrated that the OraQuick® HCV device housing was considered not to cause sensitization during contact with the oral cavity.

#### **Reactivity with HCV Seroconversion Panels**

Eighteen panels containing sequential plasma specimens from individuals undergoing seroconversion as a result of HCV infection were evaluated with the OraQuick® HCV Rapid Antibody Test and compared with an FDA approved anti-HCV EIA test. The OraQuick® HCV Rapid Antibody Test and the reference anti-HCV assay results are summarized in the following table. The sensitivity of the OraQuick® HCV Rapid Antibody Test to detect seroconversion was similar to that of the comparator EIA. The OraQuick® HCV Rapid Antibody Test detected anti-HCV antibodies earlier than EIA in 9 of the 18 seroconversion panels (50%) and by an overall average of 3.6 days (95% CI = 1.2 to 5.9).

Seroconversion Panel	Days to Evidence of HCV Infection				
	OraQuick® HCV Rapid Antibody Test		FDA approved anti-HCV EIA		Difference (OraQuick® - EIA)
	Last Non-Reactive	First Reactive	Last Non-Reactive	First Reactive	
HCV 6213	35	37	30	37	0
HCV 6214	18	23	23	25	-2
HCV 6227	46	74	46	74	0
HCV 9041	31	62	31	62	0
HCV 9046	0	69	0	69	0
HCV 9047	21	28	21	28	0
PHV 901	65	97	65	97	0
PHV 905	7	11	11	18	-7
PHV 907	7	13	13	18	-5
PHV 910 (M)	0	4	0	4	0
PHV 911 (M)	0	11	0	11	0
PHV 914	9	12	19	24	-12
PHV 916 (M)	7	9	9	23	-14
PHV 917 (M)	22	85	22	85	0
PHV 920	7	13	7	16	-3
PHV 921	0	4	4	14	-10
RP 006	388	461	461	469	-8
RP 038	47	52	52	55	-3
Average		59.2		62.7	- 3.6 (-5.9 to -1.2)

#### Reactivity with HCV Specimens from Various Genotypes and Subtypes

The ability of the OraQuick® HCV Rapid Antibody Test to detect infection derived from various genotypes and subtypes was assessed using two commercially available Worldwide HCV Performance panels. Thirty-two HCV-positive plasma specimens derived from multiple geographies, representing four genotypes (1, 2, 3 and 4) were tested. All specimens were reactive with the OraQuick® HCV Rapid Antibody Test. Three HCV-negative samples were included in the panel and all were non-reactive with the OraQuick® HCV Rapid Antibody Test.

#### Interfering Substances

The OraQuick® HCV Rapid Antibody Test was evaluated with the following interfering substances present in whole blood, samples in order to assess their potential effect on the assay performance as per CLSI guidelines EP7-A2. Testing was completed on ten HCV-negative whole blood, samples and ten HCV-positive spiked matched whole blood samples. All matched samples were spiked according to one of the following conditions as per the table below:

Interfering Substances	Concentration
Bilirubin	10 mg/dL
Hemoglobin	500 mg/dL
Lipid (Triolein)	3500 mg/dL
Protein	12 g/dL

None of these interfering substances had any impact on the OraQuick® HCV Rapid Antibody Test assay performance at the concentrations evaluated.

#### Medical Conditions Unrelated to HCV Infection

The performance of the OraQuick® HCV Rapid Antibody Test was evaluated with commercially available HCV negative plasma and serum specimens derived from medical conditions unrelated to HCV infection. Results are summarized in the table below.

Medical Condition		Non-Reactive (%)	Reactive (%)
<b>Autoimmune Diseases</b>			
Myasthenia Gravis	4	4 (100)	0 (0)
Rheumatoid Arthritis	10	10 (100)	0 (0)
Systemic Lupus Erythematosus (SLE)	10	10 (100)	0 (0)
<b>Other Medical Conditions</b>			
Influenza Vaccination	10	10 (100)	0 (0)
Hepatitis A Virus (HAV)	59	59 (100)	0 (0)
Hepatitis B Virus (HBV)	58	58 (100)	0 (0)
Hepatitis D Virus (HDV)	2	2 (100)	0 (0)
Hepatitis E Virus (HEV)	8	8 (100)	0 (0)
Epstein-Barr Virus (EBV)	10	10 (100)	0 (0)
Cytomegalovirus (CMV)	10	10 (100)	0 (0)
Herpes Simplex Virus (HSV)	10	10 (100)	0 (0)
Parvovirus B19	10	10 (100)	0 (0)
Rubella	10	10 (100)	0 (0)
Syphilis	10	10 (100)	0 (0)
Toxoplasmosis	10	10 (100)	0 (0)
Human Immunodeficiency Virus (HIV-1/2)	154	154 (100)	0 (0)
Heterophilic antibodies	10	10 (100)	0 (0)
Multiparous Female	10	10 (100)	0 (0)
<b>Total Samples Tested</b>	<b>405</b>	<b>405</b>	<b>0</b>

None of the medical conditions tested, produced false positive results in the OraQuick® HCV Rapid Antibody Test device. Performance characteristics in scleroderma, Sjögren's Syndrome and Human T-Cell Lymphotropic Virus (HTLV I/II) have not been established.

### Sample Stability

The OraQuick® HCV Rapid Antibody Test was evaluated with whole blood stored at various storage conditions over numerous days. Results are summarized in the table below.

Specimen Type	Days at Storage Condition	
	2°-8°C (36°-46 °F)	15°-30°C (59°-86 °F)
Whole Blood	7	3

Storing whole blood for up to 7 days refrigerated or 3 days at 15°-30°C (59°-86°F) did not impact the performance of the OraQuick® HCV Rapid Antibody Test.

### Specimen Types

The OraQuick® HCV Rapid Antibody Test was evaluated with whole blood samples collected in various types of anticoagulants including ethylenediaminetetracetic acid (EDTA), sodium heparin, lithium heparin, and sodium citrate. Testing was performed with twenty anti-HCV negative whole blood samples and twenty anti-HCV-spiked positive whole blood samples. All samples produced acceptable assay performance. The recommended sample collection device for use with the OraQuick® HCV Rapid Antibody Test in whole blood are vacuum tubes containing EDTA, sodium heparin, lithium heparin, sodium citrate.

### Limit of Detection Study

The limit of detection (LoD), defined as the EIA signal to cutoff ratio which yielded reactive results 95% of the time in the OraQuick® Rapid HCV Antibody Test device, was calculated for each of three (3) lots separately and for three (3) lots combined. The LoD was calculated to be 0.75 s/co using an FDA approved EIA.

### Reproducibility

The reproducibility of the OraQuick® HCV Rapid Antibody Test was tested at 3 sites using 3 lots of test devices twice a day for 5 days with 9 operators (3 per site). Three whole blood panel member types (negative, limit of detection (LoD), and low positive) were tested in 5 unique test kit types. Each test kit consisted of eight (8) blinded panel members that had various combinations of the 3 panel members in a randomized sequence. Panel members were blinded per operator, run, and device lot to ensure that the results of the panel member types were unpredictable to the operator. LoD specimen was determined to be a 0.75 s/co by an FDA approved EIA. Overall concordance across operators, sites, and device lots was 98.9% (95% CI 97.9-99.5%) for the negative specimen, 98.7% (95% CI 97.6-99.4%) for the specimen at the limit of detection and 99.7% (95% CI 99.0-100.0%) for the low positive specimen.

### Stability Studies

Two stability studies, comprised of three (3) validation lots each, are ongoing to evaluate the OraQuick® HCV Rapid Antibody Test shelf life and the OraQuick® HCV Rapid Antibody Test Kit Control shelf life. The OraQuick® HCV Rapid Antibody Test Kit Control study also includes an open vial stability evaluation.



The data from the stability study for the OraQuick® HCV Rapid Antibody Test substantiates a shelf life of eighteen (18) months at storage conditions of 2° - 30°C (36° - 86°F).

The data from the stability study for the OraQuick® HCV Rapid Antibody Test Kit Controls substantiates a twelve (12) month shelf life at storage conditions of 2° - 8°C (36° - 46°F). Once opened, the OraQuick® HCV Rapid Antibody Test Kit Controls have an eight (8) week shelf life at storage conditions of 2° - 8°C (36° - 46°F).

#### Shipping Studies

The OraQuick® HCV Rapid Antibody Test (Pouched Assay – Device and Developer Solution) is packaged in 25-count or 100-count preprinted boxes including an equivalent number of loops for blood testing, reusable OraQuick® Test stands, and package insert.

A shipping study was performed to confirm that the external packaging configuration for the OraQuick® HCV Rapid Antibody Test provided a high probability of safe and intact arrival at its destination. The study was designed to confirm that the integrity of the packaging and its components could withstand the simulated shipping and handling stresses and to demonstrate that the shipping and handling stresses had no adverse effect on the OraQuick® HCV Rapid Antibody Test performance.

The OraQuick® HCV Rapid Antibody Test Kit Controls are comprised of an HCV Positive Control, and an HCV Negative Control packaged in a Control Box with its Package Insert. The Control Box is then placed in an insulated outer shipping carton. A shipping study was performed to confirm that the external packaging configuration for the OraQuick® HCV Rapid Antibody Test Kit Controls provided a high probability of safe and intact arrival at its destination. The study was designed to confirm that the integrity of the packaging and its components could withstand simulated shipping and handling stresses and to demonstrate that the shipping and handling stresses had no adverse effect on the OraQuick® HCV Rapid Antibody Test Kit Control performance.

#### **B. Animal Studies**

Not Applicable

#### **C. Additional Studies**

Not Applicable

### **X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)**

Two multi-center prospective studies were conducted to evaluate the clinical performance of the OraQuick® HCV Rapid Antibody Test in subjects with signs or symptoms of hepatitis and subjects at risk for hepatitis C infection. These risk factors included past or present intravenous drug use, having received a blood transfusion or organ transplant

prior to 1992, evidence of high-risk sexual behavior, being born to an HCV positive mother, having been on long-term hemodialysis, history of incarceration, and positive for HIV status. Clinical performance was evaluated in venipuncture whole blood specimens from subjects prospectively enrolled at 8 geographically dispersed centers within the United States.

The population tested was African American (43.0%), Caucasian (37.7%), Hispanic/Latino (17.1%), as well as a small proportion of other ethnic groups (2.2%). The mean age was 45 years (age range: 15 to 84 years). Of the 1207 subject specimens tested, 436 were HCV infected, 762 were negative, and 9 specimens had the status of "Unable to Determine". HCV status was determined for each subject by EIA, with supplemental RIBA<sup>®</sup> and PCR assays as required. The table below summarizes the distribution of OraQuick<sup>®</sup> HCV Rapid Antibody Test reactive, non-reactive, and invalid results in subject with HCV infected stats per the reference laboratory testing algorithm.

OraQuick <sup>®</sup> HCV Rapid Antibody Test Results	Subject HCV Infected Status		
	Positive	Negative	Unable to Determine Infected Status
Positive	435	0	8
Negative	1	762	1
Invalid	0	0	0

#### Positive and Negative Agreement Calculations

Percent positive and percent negative agreement between the OraQuick<sup>®</sup> HCV Rapid Antibody Test and HCV status were calculated overall for the per protocol population (n=1207), as well as for subjects with signs or symptoms of hepatitis and subjects at risk for hepatitis C infection.

Percent Positive Agreement =  $\frac{\text{Number of OraQuick<sup>®</sup> HCV Rapid Antibody Test Reactive Results}}{\text{Total number of HCV Infected status}} \times 100$

Percent Negative Agreement =  $\frac{\text{Number of OraQuick<sup>®</sup> HCV Rapid Antibody Test Non-Reactive Results}}{\text{Total number of HCV Not Infected status}} \times 100$

For the purposes of calculating percent agreement, OraQuick<sup>®</sup> HCV Rapid Antibody Test reactive results for samples whose HCV status was "Unable to Determine" following EIA with supplemental RIBA<sup>®</sup> and PCR testing were considered "HCV Not Infected", and OraQuick<sup>®</sup> HCV Rapid Antibody Test non-reactive results for samples whose HCV status was "Unable to Determine" following EIA with supplemental RIBA<sup>®</sup> and PCR testing were considered "HCV Infected".

### Positive and Negative Agreement

The percent positive and negative agreement between the OraQuick® HCV Rapid Antibody Test and the subject HCV Infected Status was calculated for the per protocol population (n=1207). Percent positive and negative agreement was also calculated for at risk individuals with signs or symptoms of hepatitis (n=142), and for individuals without signs or symptoms of hepatitis (n=1064). Percent positive and negative agreement according to risk factors for HCV infection was also calculated. The risks for HCV were ranked on a clinical evaluation of the likelihood of acquiring hepatitis C, with the most common given higher rankings.<sup>3</sup> Each subject was assigned only one risk (the highest). Results with the 95% confidence intervals are summarized in the following table.

Study Subjects	Total	Positive Percent Agreement	95% Exact Confidence Interval	Negative Percent Agreement	95% Exact Confidence Interval
Overall	1207	99.5%* (435 / 437)	98.4, 99.9	99.0%* (762 / 770)	98.0, 99.6
Overall with signs or symptoms	142	100.0 (54 / 54)	93.4, 100.0	100.0% (88 / 88)	95.9, 100.0
Overall without signs or symptoms	1064	99.5%* (381 / 383)	98.1, 99.9	98.8%* (673 / 681)	97.7, 99.5
IVDU	456	99.3% (291 / 293)	97.6, 99.9	98.2% (160 / 163)	94.7, 99.6
Dialysis	6	100% (1 / 1)	2.5, 100.0	100.0% (5 / 5)	47.8, 100.0
Transfusion/Transplant	63	100.0% (16 / 16)	79.4, 100.0	100.0% (47 / 47)	92.5, 100.0
High Risk sex	461	100.0% (58 / 58)	93.8, 100.0	98.8 (398 / 403)	97.1, 99.6
HCV positive mother	2	100.0% (1 / 1)	2.5, 100.0	100.0% (1 / 1)	2.5, 100.0
Prior history of incarceration	56	100% (11 / 11)	71.5, 100.0	100.0% (45 / 45)	92.1, 100.0
HIV positive <sup>§</sup>	17	100.0 (2 / 2)	15.8, 100.0	100.0% (15 / 15)	78.2, 100.0
None specified	3	100.0% (1 / 1)	2.5, 100.0	100.0% (2 / 2)	15.8, 100.0

\*Includes subjects with "unable to determine" status.

§Does not include 377 additional HIV positive subjects enrolled but included in higher ranked risk categories, and 6 HIV positive subjects enrolled with signs or symptoms of hepatitis.

Results of Supplemental Testing of Specimens Reactive in the OraQuick® HCV Rapid Antibody Test

The table below shows the results obtained when subjects reactive in the OraQuick® HCV Rapid Antibody Test were tested by recombinant immunoblot assay (RIBA®).

Number of OraQuick Reactive Results	RIBA®		
	Positive	Indeterminate	Negative
443	418	25*	0

\*Seventeen (17) of the RIBA® indeterminate results were positive for HCV RNA when tested by PCR.

Of the subjects reactive in the OraQuick® HCV Rapid Antibody Test, 94.4% (418/443) were positive by RIBA®. Seventeen (17) of the twenty-five (25) RIBA® indeterminate results were positive for HCV RNA when tested by PCR.

**XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION**

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Microbiology an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

**XII. CONCLUSION.S DRAWN FROM PRECLINICAL AND CLINICAL STUDIES**

The data from the non-clinical studies demonstrated acceptable positive and negative agreement, seroconversion panel detection, and genotype detection of the OraQuick® HCV Rapid Antibody Test, when used according to the instructions for use as stated in the labeling. The clinical studies in this application indicate that the OraQuick® HCV Rapid Antibody Test is safe and effective when used according to the directions for use in the labeling.

**A. Overall Conclusions**

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

**XIII. CDRH DECISION**

CDRH issued an approval order on June 25, 2010.

The applicant's manufacturing facility(ies) was/were inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

**XIV. APPROVAL SPECIFICATIONS**

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

**XV. REFERENCES**

1. CDC, Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings. MMWR 1988; 37(24):377-388.
2. CDC, Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001; 50 (RR-11):1-42.
3. CDC, Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV – Related Chronic Disease. MMWR 1998; 47(RR19): 1-39.